

SUPPORTING
THE FUTURE
SINCE 1870

INTELLECTUAL PROPERTY RIGHTS

BB2170 COURSE IN DRUG DEVELOPMENT

KTH, STOCKHOLM

Hampus Rystedt, *M. Sc., LL.M*
European Patent Attorney
Zacco Sweden AB
hampus.rystedt@zacco.com

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WHY DO YOU NEED TO KNOW ABOUT PATENTS?





WHY ARE YOU LEARNING ABOUT DRUG DEVELOPMENT?

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HOW CAN YOU ACHIEVE YOUR GOALS?

Discovery and validation of drug targets
Preparation of diagnostic reagents and
pharmaceuticals ready for the market

- You will need money -

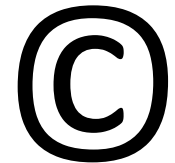
HOW CAN YOU MAKE MONEY OUT OF AN IDEA?

- Sell or license the idea
- Sell a product or service based on the idea
 - Market share
 - Premium price
- Use the idea as a bargaining chip for e.g.
 - Access to market, as big as possible
 - Access to tech to make and deliver product/service
 - Access to capital

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PROTECT YOUR IDEA TO PREVENT COPYING

- Intellectual Property Rights (IPR)
 - Protects "creations of the mind"
- Different forms of IPR, e.g.
 - Patent: technical solution, invention
 - Utility model: like patents, for simple inventions
 - Design: specific design of product, package
 - Trade mark: identity of seller or product
 - Copyright: literary/musical/artistic work, source code



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ONE PRODUCT - SEVERAL FORMS OF PROTECTION

Trade mark

3 NICOTINELL




Trade mark No: 005232574
Filing date: 01/08/2006
Nice Classification: 5
Name of the owner: Novartis AG
Applicant's reference: 1649/06RNH/MBW
Trade mark basis: CTM

Type of mark: Figurative
Date of registration: 08/11/2007
Status: Registered
Publication of registration ☒

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ONE PRODUCT - SEVERAL FORMS OF PROTECTION


Patent

(19)	 Europäisches Patentamt European Patent Office Office européen des brevets	 (11) EP 0 906 089 B1
(12)	EUROPEAN PATENT SPECIFICATION	
(45)	Date of publication and mention of the grant of the patent: 27.08.2003 Bulletin 2003/35	(51) Int Cl.7: A61K 9/20
(21)	Application number: 97922974.7	(86) International application number: PCT/EP97/02299
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(54)	BUCCAL DELIVERY SYSTEM MUNDFREISETZUNGSSYSTEM SYSTEME DE LIBERATION BUCCAL	
(84)	Designated Contracting States: AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE	(74) Representative: Grubb, Philip William et al Novartis AG, Corporate Intellectual Property, Lichtstrasse 35 4002 Basel (CH)
(30)	Priority: 13.05.1996 EP 96810303	

ONE PRODUCT - SEVERAL FORMS OF PROTECTION

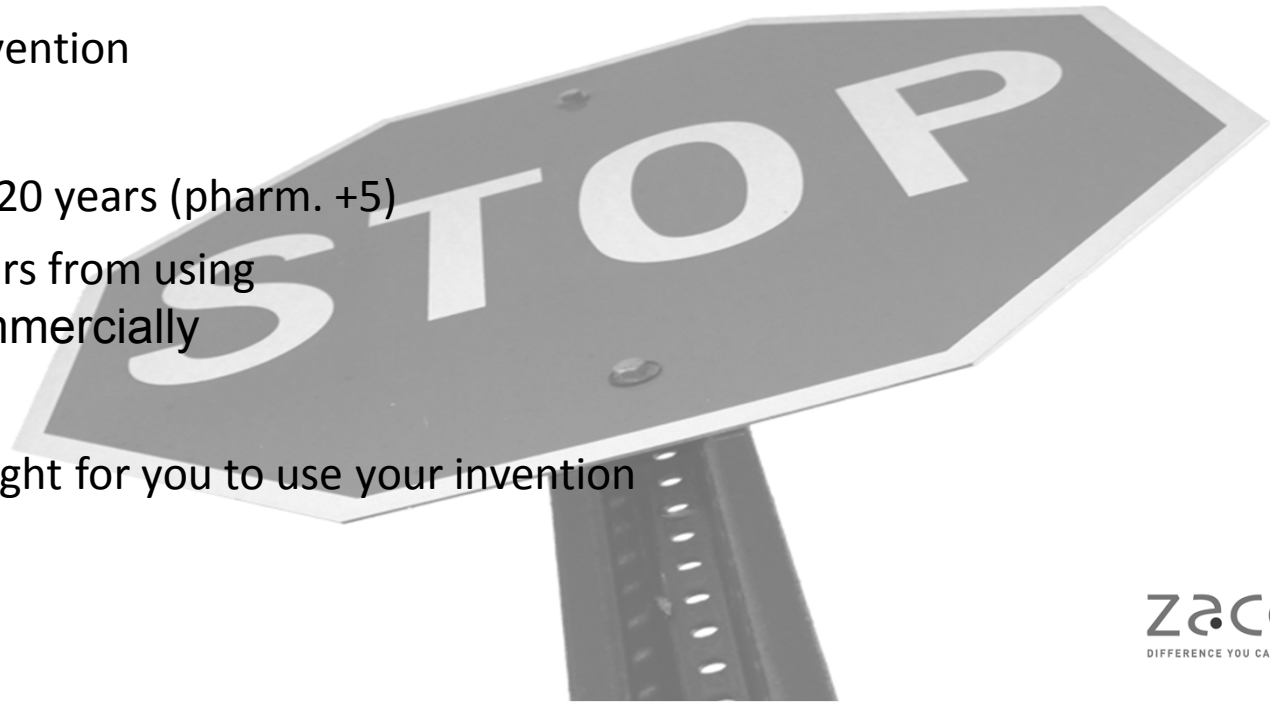
Design

Design	
Filing date:	06/06/2006
Registration date:	06/06/2006
Publication date (A1):	18/07/2006
Expiry date:	06/06/2016
Locarno class-subclass:	09.03 (EUROLOCARNO)
Verbal element:	NICOTINELL
Vienna classification:	19.3.25 (Vienna classification)
Status:	Registered and fully published (A1) (Glossary)
Language of filing:	English
Second language:	Italian

Representation	
0001.1	
0001.2	
0001.3	

WHAT IS A PATENT?

- Protection of an invention
 - A national right
 - A temporary right: 20 years (pharm. +5)
 - A right to stop others from using your invention commercially
- ★ A patent is NOT a right for you to use your invention



WHY DOES SOCIETY GRANT PATENTS?

- To stimulate innovation and technological development
- Society gets to publish the invention
- Society rewards inventor by granting a temporary monopoly
- Competitors forced to find other solutions

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FAIR BALANCE

There must be a fair balance
between the technical contribution
disclosed in the patent
and the scope of monopoly

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CRITERIA FOR PATENTABILITY

- Invention - NOT just a discovery.

Example:

Discovery: A previously unknown protein

Invention: The technical/medicinal effect arising from a specified use of the previously unknown protein

- Industrial applicability
- Novelty
- Inventive step

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WHAT CANNOT BE PATENTED?

- Discoveries, scientific theories and mathematical methods
- Aesthetic creations
- Schemes, rules and methods for performing mental acts, playing games or doing business,
- Computer programs as such
- Presentations of information

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INDUSTRIAL APPLICABILITY

- Made or used in any kind of industry, including agriculture
- Seldom questioned, but relevant for patenting of drug targets
 - For any nucleic acid sequence, explain its technical / industrial use
 - For gene and protein sequences, state their biological function, and give evidence in the form of experimental data

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WHAT CAN BE PATENTED?

- Product
 - Substance (e.g. chemically synthesized compound or gene sequence)
 - An element **isolated** from the human body or produced by technical means, including a gene/protein sequence or an organ produced by cell culture in vitro.
 - Composition
 - Microorganism
 - Diagnostic kit

WHAT CAN BE PATENTED?

- Method, e.g.
 - Method of preparing a product
 - Method of using a product or apparatus
- Use of a product or apparatus or method for a specified purpose
- Use of a known drug for a new therapeutic indication
- Apparatus
 - A claim to a product or apparatus protects all potential uses to which the product can be applied

EXCEPTIONS TO PATENTABILITY

- Commercial exploitation contrary to "ordre public" or morality
- Plant or animal varieties or essentially biological processes for the production of plants or animals
- Methods for treatment of humans or animals by surgery or therapy, and diagnostic methods practised on the human or animal body
- *In some countries, e.g. the US, methods for treatment are patentable*

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NOVELTY

- Novel (= new) in relation to what is known the day before the filing of a patent application
- Known = publicly available
- Any means of publication: scientific publications, posters at conferences, testing without secrecy, oral presentations, applications for grant of money filed with Swedish authorities
- Published anywhere in the world, in any language
- An invention lacks novelty if each element of the invention is disclosed in a single publication

INVENTIVE STEP

Not obvious to a person of ordinary skill in the technical field of the invention
"obvious" = follows plainly and logically from what is known the day before
the filing of a patent application, e.g. from known routine experiments
Inventive = goes beyond the normal progress in the technical field, involves
unexpected effects

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THE PATENT APPLICATION - FORMAT

- Title
- Description: at least one way of performing the invention, must be enabling
- Figures: if needed to understand invention
- Claims: defining the legal protection of the patent
- Sequence listing: if amino acid or nucleotide sequences in the patent application
- Abstract
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DESCRIPTION

Must be sufficiently detailed to

- allow the person skilled in the art to work the invention in the entire claimed scope, and
- show that the inventor actually had made the invention at the time of filing

The description should comprise

- Technical field of the invention
- Background/prior art/known technology
- Summary of the invention
- Brief description of the drawings
- Detailed description of the invention
- Examples/experiments showing that the invention works

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DESCRIPTION, NEW LMW SUBSTANCE WITH ANTI-CANCER ACTIVITY

Technical field: “Drugs, especially for treatment of cancer”

Background: Describe existing treatments of cancer, especially drug therapies

Summary: Generic formula of substance, preferred cancer types to be treated.

Detailed description: Protocol for synthesizing substance class, experiments showing synthesis of as many specific substances as possible, experiments indicating therapeutic effect, reasoning supporting broad protection

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CLAIMS

The claims define the extent of protection

Thus, it is important that the claims define the invention

May be directed to products, methods or uses (use-claims not accepted in the U.S.)

The claims are interpreted in the light of the description (and file prosecution history in e.g. U.S. and Sweden)

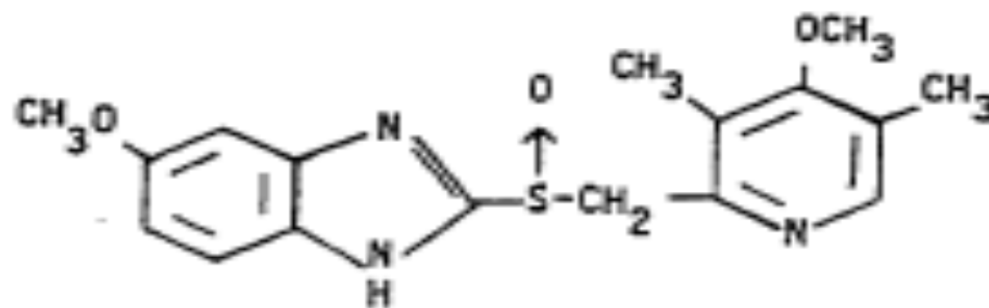
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CLAIM STRUCTURE, EXAMPLE

1. Pharmaceutical composition comprising an analgesic, a central-nervous system stimulant and optionally pharmaceutically acceptable carriers and/or excipients.
2. Composition according to claim 1, wherein the analgesic is acetyl salicylic acid.
3. Composition according to claim 1 or 2, wherein the CNS stimulant is caffeine.

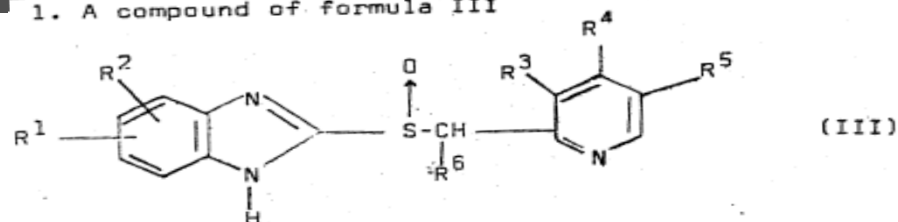
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EXAMPLE, OMEPRAZOLE (LOSEC®)



EXAMPLE, OMEPRAZOLE, EP 5129, B1

1. A compound of formula III



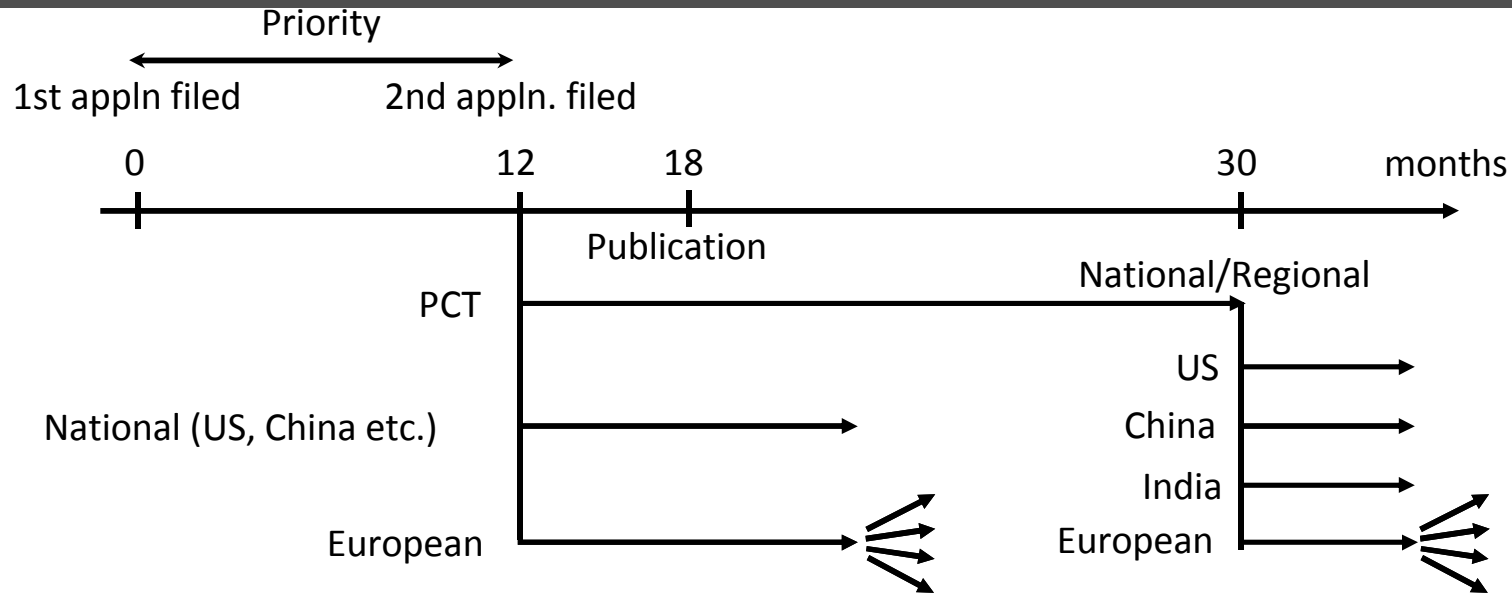
or a therapeutically acceptable salt thereof in which R^1 and R^2 are the same or different and are selected from the group consisting of hydrogen, alkyl, halogen, carbomethoxy, carboethoxy, alkoxy, and alkanoyl in any position, R^6 is selected from the group consisting of hydrogen, methyl and ethyl, R^3 , R^4 , and R^5 are the same or different and are each selected from the group consisting of hydrogen, methyl, methoxy, ethoxy, methoxy-ethoxy and ethoxy-ethoxy whereby R^3 , R^4 , and R^5 are not all hydrogen, and whereby when two of R^3 , R^4 , and R^5 are hydrogen, the third of R^3 , R^4 , and R^5 is not methyl.

IMPORTANT:

In general, you are not allowed to add any information to the patent application once it has been filed.

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OVERVIEW PATENT PROCESS



- PCT = Patent Cooperation Treaty

OVERVIEW PATENT PROCESS

- IN EACH COUNTRY

1. Applicant files the patent application at a patent office
2. Patent office examines the application and issues an examination report
3. Applicant may reply with arguments and with amended (changed) claims.
Applicant may request oral proceedings
4. Patent office may issue further examination reports and/or hold oral proceedings
5. Patent office grants or refuses the application.

In many countries, anyone may oppose a granted patent within a specified period after grant.

You can appeal a decision which is negative for you

BEFORE FILING A PATENT APPLICATION, ASK YOURSELF:

- In your opinion, is the invention new and inventive?
- Do you have support in the form of experimental data?
- Do you need to make it publicly available (now/anytime) or can you keep it as a trade secret?
- Is it worth protecting? Will you make money out of it? Will it block competitors?

FREEDOM TO OPERATE

- Do you have freedom to operate, freedom to practice your invention?
- Are there patents owned by third parties that you would infringe if you start practicing a particular technology?
- Search for granted patents relating to that technology, check the claim scope and if the patents are valid

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IPR CREATES VALUE

- Protect present and future products
- Block, confuse or threat competitors
- Licensing, cross-licensing, sale of IPR
- Publicity
- Improved reputation among investors
- Improved reputation among customers
- Recognition of employees' efforts

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